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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,304	12/12/2003	Ernest G. Roden	144005.00201	9951

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James Remenick
Powell Golstein LLP
Intellectual Property Group
901 New York Avenue, N.W., Third Floor
Washington, DC 20001-4413

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,304	RODEN ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *98-103* is/are allowed.

6)☒ Claim(s) *43-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,375,976 ('976). Although the conflicting claims are not identical, they are not patentably distinct from each other because US '976 claims an acidic solution for inhibiting microbial growth consisting essentially of an aqueous acidic core composition, said acidic solution comprising from about 50 to about 100 percent of said acidic core composition, said acidic core composition consisting of three acids that are ingestible and thereby safe for use in food and drink products and food- and drink-associated products, said acid core composition prepared by the steps of: admixing from about 1 to about 5 volume percent

of a first acid, said first acid being an inorganic acid that dissociates nearly to completion in water, with about 5 to about 10 volume percent of a second acid, said second acid being an inorganic acid less strong than said first inorganic acid, said second acid having a dissociation constant of less than about 10.sup.-1, to produce a first acidic composition; and admixing from 6 to about 10 weight percent of a hydroxy acid, having at least twice the chelating capability of said first and second acids, with water to produce a second acidic composition; and admixing said first acidic composition with said second acidic composition to produce said acid core composition having a pH of less than one and wherein said acidic core composition will not react with human tissue. Hydrochloric acid, phosphoric acid, and citric acid are found in claims 2-4 and 24. Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of US '976 to obtain the claimed invention, because the patent teaches using similar GRAS acids to obtain at least a similar acid formulation for the same purpose.

Claims 43-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 29-43 and 47-55 of copending Application No. 10/118360 ('360). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '360 claims a pharmaceutical compound comprising a three acid composition and a carrier, said three acid composition consisting an aqueous solution of first, second, and third GRAS [[acid]] acids, said pharmaceutical compound prepared by the process comprising: mixing a first GRAS acid, said first GRAS acid being an inorganic acid that

dissociates nearly to completion in water, with a second GRAS acid, said second GRAS acid being an inorganic acid less strong than said first inorganic acid and having a dissociation constant of less than about 10-1, to produce a homogeneous mixture, wherein the amount of the second GRAS acid is greater than or equal to the amount of the first GRAS acid; and admixing a third GRAS acid with the homogeneous mixture, said third GRAS acid being an organic acid weaker than said first and second acids, said third acid having a dissociation constant of from about 10^{-1} to 10^{-5} and having chelating capability of at least twice said first and second inorganic acids; and admixing a pharmaceutical carrier with the three acid composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of the co-application to obtain the claimed invention, because application '360 teaches using similar GRAS acids to obtain at least a similar acid formulation for the same purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Garcia WO 97/40670.

Garcia discloses a low pH acidic composition comprising a first acid being an inorganic acid that dissociates essentially completely in water; a second acid being an inorganic acid but not as strong as the first acid and having dissociation constant of less than about 10^{-1}, a third acid being an organic acid having dissociation constant of between about 10^{-1} and about 10^{-5}, and a fourth acid being an organic acid (see abstract; page 3, lines 33-page 4, lines 1-9; and claims 1 & 6). The acid composition is used as a core component in pharmaceutical compositions, and cosmetic compositions (page 4, lines 10-14). For example, the pharmaceutical compositions which are useful in the topical treatment of infections caused by bacterial, viral, and fungal agents comprise blended of two basic phases; the first phase comprising agents such as active ingredients including topical anesthetics, surfactants, vitamin E, or wetting agents, and the second phase comprising the low pH acidic composition (page 7, lines 15 through page 8, lines 1-23). Garcia further discloses first acid is hydrochloric acid, second acid is phosphoric acid, and citric acid is the fourth acid (page 4, line 31; page 5, lines 9-16; and page 6, lines 1-3).

The use of the transitional phrase "consisting essentially of" is noted. However, Garcia is different only in the sense that Garcia teaches the use of a fourth acid. However, the fourth acid of Garcia is equivalent to the third acid of the present composition, *e.g.*, citric acid. Further, the third acid taught by Garcia is selected from acid that is similar to the fourth acid. More specifically, Garcia teaches a four acid composition that has the same properties and purposes desired by the present invention, namely, acid composition useful pharmaceutical and cosmetic arts (page 4,

lines 10-14). For example, topical treatment of infections caused by bacterial, viral, and fungal agents comprise blended of two basic phases; the first phase comprising agents such as active ingredients including topical anesthetics, surfactants, vitamin E, or wetting agents, and the second phase comprising the low pH acidic composition (page 7, lines 15 through page 8, lines 1-23). It is noted that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials *"and those that do not materially affect the basic and novel characteristic(s)"* of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select any acids to obtain a formulation that is safe and effective for the same purpose, namely composition useful in pharmaceutical art, because Garcia teaches the use of the same three acids, having the same dissociation constant, *e.g.*, hydrochloric acid (first acid), phosphoric acid (second acid), and citric acid (third acid) for the same purpose, *e.g.*, pharmaceutical formulation. The present of the fourth acid does not appear to place any detrimental effect in the desirability of obtaining a safe and useful acid composition effective for the treatment of contaminated surfaces.

It is noted that Garcia does not explicitly teach the compound is safe for human ingestion. However, it is the position of the examiner that such limitation is inherent, because Garcia discloses the use of the same compound, and because Garcia discloses the compound can be used for the treatment of the drinking water (page 10, lines 1-6). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Further, the burden is shifted to applicant to show that the acid composition of Garcia is not safe for human ingestion.

Claims 43-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walzer US 4,199,469.

Walzer discloses a method for cleaning surfaces which are contaminated by algae, microorganisms, and ochre sediments comprising contacting the surfaces with an aqueous solution comprises hydrochloric acid (first acid), phosphoric acid (second acid), and citric acid (third acid) (column 1, lines 5-13; and column 2, lines 1-11, lines 44-50).

In view of the transitional phrase "consisting of", Walzer is different only in the sense that Walzer teaches the use of more than three acids. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select any acids to obtain a formulation that is safe and effective for the same treatment, namely

decontaminating surfaces, because Walzer teaches the use of the same three acids, *e.g.*, hydrochloric acid (first acid), phosphoric acid (second acid), and citric acid (third acid) for the same purpose, *e.g.*, decontaminating surfaces of tanks for drinking water. The present of formic acid and ascorbic acid does not appear to place any detrimental effect in the desirability of obtaining a safe and useful acid composition effective for the treatment of contaminated surfaces. Thus, it is the position of the examiner that ascorbic acid and formic acid are materials that do not materially affect the basic and novel characteristics of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 90 USPQ 461, 463 (CCPA 1976).

It is noted that Walzer does not explicitly teach the compound is safe for human ingestion, as well as the dissociation constant of the acids. However, it is the position of the examiner that such limitations are inherent, because Walzer discloses the use of the same acids, *e.g.*, hydrochloric acid (first acid), phosphoric acid (second acid), and citric acid (third acid), and because Walzer discloses the acid composition can be used for the treatment of tanks for drinking water. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to applicant to show that the acid composition of Walzer is not safe for human ingestion.

Claims 43-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia EP 0 148 709, in view of Charles G. Hurst, M.D. (Decontamination), and York US 4,778,457.

Garcia discloses a method for treating tissue infection caused by bacteria, virus, fungus or yeast, comprising topically applying to the infected tissue with a composition comprising hydrochloric acid (first acid), phosphoric acid (second acid), and citric acid (third acid) (see abstract; page 2, lines 16-19; page 4, lines 1-5; pages 6-8, lines 1-8; and example 1). Garcia further teaches any suitable method can be employed in the application of composition to the infected tissue, such as cotton swab, spray, and the like (page 10, lines 25-28).

Garcia does not explicitly teach the infected tissue such as eye. Furthermore, Garcia is silent as to the teaching of sponge and towelette.

Dr. Hurst teaches decontamination of infected tissue includes the skin and eye (see page 352, column 1; and page 353, columns 1-2). Dr. Hurst further teaches a decontamination method using adsorbent materials, such as paper towel, or non-woven pad (page 354, columns 1-2). York teaches a disposable applicator for treating blepharits in the human eye using a porous sponge impregnated with at least one antimicrobial agent (see abstract). Thus, it would have been obvious to one of ordinary skill in the to modify the acid composition of Garcia for the treatment of the eye using adsorbent materials such as sponge in view of the teaching of Dr. Hurst and York, because Dr. Hurst teaches methods of decontamination including the use of aqueous solution containing acids (pages 354-355), because York teaches decontamination

solution can be applied using sponge or applicator, because Garcia teaches a pharmaceutical acid composition having broad application in the treatment of infection such as topical treatment of infected tissue (page 3), because Garcia teaches a pharmaceutical acid composition in combination with a carrier vehicle that is substantially inert to healthy tissue and do not attack or damage the healthy tissue surrounding infected tissue (pages 4 & 9), because Garcia teaches that the concentration of the acid composition can be modified/selected depend upon the desirable purpose of application (page 10), and because Garcia teaches any suitable method can be used in the application of composition to the infected tissue, such as cotton swab, spray, and the like (page 10, lines 25-28).

Claims Allowable

Claims 98-103 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615